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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,493	12/28/2000	Mark A. Burns	UM-04985	3280

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EXAMINER

SISSON, BRADLEY L

ART UNIT PAPER NUMBER

1634

DATE MAILED: 07/03/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/751,493

Applicant(s)

BURNS ET AL.

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Location of Application

1. The location of the subject application has changed. The subject application is now located in Group 1630, Art Unit 1634.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06 May 2002 has been entered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-20 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method of claims 1-12 as found in US Patent 6,057,149, as well as for the device found in claims 1-3 of US Patent 6,271,021, does not reasonably provide enablement for a device where it is manufactured out of quartz or glass. The

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specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

5. As presently worded, the invention of claims 1-20 has been interpreted as encompassing a device where the support does not have to be made of silicon, but can comprise materials such as glass and quartz. At page 6 of the specification it is noted that silicon is disclosed as the material that the substrate is to be comprised of. More specifically, the specification states:

The present invention contemplates a method for moving microdroplets, comprising: (a) providing a liquid microdroplet disposed within a microdroplet transport channel etched in silicon.... (Emphasis added)

At page 12 the specification effectively teaches away from using substrates other than silicon.

As stated there:

While other substrates, such as glass and quartz, can use photolithographic methods to construct microfabricated analysis devices, only silicon gives the added advantage of allowing a large variety of electronic components to be fabricated within the same structure.

It is noted with particularity that independent claims 1 and 8 require that an array of heating elements be arrayed along the microchannels (independent claim 13 places no restriction on the substrate material). A review of the specification finds that at page 13, second paragraph, silicon micromachining is disclosed. The specification has not been found to disclose other suitable means for fabricating the claimed device in substrates such as glass and quartz. While Figure 2 does depict a device that comprises a glass substrate, it is noted with particularity that the microchannels are not to be found in the glass, but rather, are found in silicon that is bonded to the glass (specification at page 13, last paragraph). Also, at page 31, third paragraph, the specification teaches that in order "[t]o form a biologically compatible heating element, the

present inventors began by coating a standard silicon wafer with 0.5 μm layer of silicon dioxide....”

6. The specification has not been found to set forth a reproducible procedure whereby by any other substrate can be ~~used~~ to manufacture the claimed device nor has the specification been found to disclose how a device, manufactured in a substrate other than silicon, can be used with biological materials. B.B.

7. In view of the explicit teachings away from using other materials, and given the limited guidance provided, the specification has not been found to satisfy the enablement requirement of 35 USC 112, first paragraph.

8. Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. A review of the specification finds an adequate written description of only a device where the microchannels and heating arrays have been synthesized in a silicon substrate, e.g., device of claims 1-3 of US Patent 6,271,021. The specification has been found to effectively teach away from producing the claimed device in substrates in glass or quartz; *supra*. In view of the limited, yet specific guidance provided, the specification does not reasonably suggest that applicant was in possession of the claimed device where the substrate is a material other than silicon.

Response to arguments

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9. At page 4, last paragraph, bridging to page 6 of the response received 06 May 2002 it is asserted that the instant disclosure does provide support for other embodiments, directing attention to pages 13 and 21-24, and reproducing a portion of page 12.

10. The above arguments and noted passages have been fully considered and have not been found persuasive towards the withdrawal of the rejections of claims under 35 USC 112, first paragraph. While agreement is reached in that the specification does teach of using other substrates such as glass and quartz (specification at page 12), it is noted that the specification effectively teaches away from using these alternative embodiments, and does positively direct one to use silicon as applicant notes that only silicon allows one to place a variety of electrical components on/in its surface, and only silicon has been disclosed as allowing for the creation of "biologically compatible heating elements." Claims 1-20 require an array of heating elements and page 5, third paragraph states in part:

The present invention relates to microfabrication of microscale devices and reactions on microscale devices, and in particular, movement of biological samples in microdroplets through microchannels to initiate biological reactions. (Emphasis added)

Clearly, the claimed device is intended, at least at the time of filing, to be directed to biological reactions, and that this same specification only teaches the use of a silicon substrate while at the same time teaching away from using other substrates, *i.e.*, glass and quartz.

11. For the above reasons, and in the absence of convincing evidence to the contrary, the specification has not been found to either enable the enablement or written description requirements of 35 USC 112, first paragraph.

Conclusion

12. Rejections which appeared in the prior Office action and which were not reproduced hereinabove have been withdrawn.

13. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

14. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

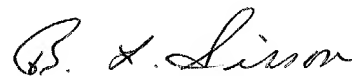
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16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

17. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
July 1, 2002